



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,649	03/30/2001	Edward Soh Smith	RPA1006	8561

22829 7590 09/27/2004

ROCHE MOLECULAR SYSTEMS INC
PATENT LAW DEPARTMENT
1145 ATLANTIC AVENUE
ALAMEDA, CA 94501

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,649

Applicant(s)

SMITH ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8-16,20-32,36-44 and 48-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-16,20-32,36-44 and 48-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed June 28, 2004. Currently, claims 1-4, 8-16, 20-32, 36-44, 48-68 are pending.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28, 2004 has been entered.
3. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
4. Any objections and rejections not reiterated below are hereby withdrawn in view of applicant's arguments. The enablement rejection has been reconsidered with respect to the instant claims and their extreme breadth, such that prior art has been applied. In the event that the claims are narrowed, the examiner may wish to reconsider the new claims and any enablement issues.
5. This action contains new grounds of rejection.

Priority

6. This application claims priority to provisional application 60/198,336, filed April 18, 2000.

Claim Objections

7. Claim 53, 57, 61, 65 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1, 13, 29, 41. Claim 1 and 53 appear to be identical, Claims 13 and 57 appear identical, Claim 29 and 61 appear to be identical and Claims 41 and 65 appear identical. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-4, 14-16, 30-32, 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A1) Claims 2-4, 14-16, 30-32, 42-44 are indefinite because the claims do not appear to be encompassed within Claim 1. Specifically, Claim 1 requires that the amino acid at position 40 of said amino acid sequence is mutated in comparison to said native

Art Unit: 1634

sequence to an amino acid OTHER than E, A, G or P. SEQ ID NO: 2 is LSXELXIPYEE. SEQ ID NO: 3 is LSQELAIPYEE. SEQ ID NO: 4 is LSXELSIPIYEE. Each of these sequences comprise an E at position 4 which is explicitly excluded from Claim 1. Thus, it is unclear how Claim 3 and 4 can limit claim 1. It is unclear whether Claims 3 and 4 are intended to require that SEQ ID NO: 3 and 4 are the "native form of DNA polymerase" prior to the mutations or whether the mutant polymerase comprises SEQ ID NO: 3 and 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-2, 4, 13-14, 16, 29-30, 32, 41-42, 44, 53, 57, 61, 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergquist et al (WO 95/14770, June 1995).

Bergquist teaches SEQ ID NO: 1, 2, 4 and 14 of the instant application.

Bergquist teaches that the invention comprises a thermophilic enzyme which is used in PCR and RT/PCR amplifications. All PCR reactions were performed in Tris-HCL, MgCl₂ with nucleotides, primers and DNA polymerase and template (page 12).

Art Unit: 1634

Bergquist teaches that the reverse transcriptions were performed at 60C and allowed to proceed (page 12). Bergquist teaches that Taq polymerase and Tth polymerase require Mn²⁺. Tfil polymerase shows the same high level of reverse transcriptase activity as Tth pol but differs in that no activity is obtained when MnCl₂ was used instead of MgCl₂ for reverse transcription (page 18). The polymerase is taught to be useful in RT-PCR assays.

Bergquist further teaches that the polymerase comprises LSDRIHLLHPE. This polymerase comprises an amino acid sequence of L[SA].[-EAGP][LI].....E as required by Claim 1, 13, 29, 41. The amino acid sequence is located in Figure 1-1 on the line beginning with 421 (limitations of Claim 1).

As seen in Figure 1-3, the critical motif of SEQ ID NO: 4 is also present, namely LSQELSIPEE. Although this motif comprises an E at position 4 which is specifically excluded by Claim 1, Claim 4 requires SEQ ID NO: 4 which also has an E at position, thus, the rejection is applied in the event that the independent claim is amended to all for an E at position 4.

10. Claims 1, 8, 12-13, 20, 24-29, 36, 40-41, 48, 52-54, 57-58, 61-62, 65-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfand et al. (US Pat. 5,374,553, December 1994).

Gelfand-1994 teaches a purified thermostable enzyme from *Thermotoga maritima* (limitations of Claim 8, 20). The enzyme comprises LSVRLGVPKVE (positions 741-751 of sequence at col. 7-8)(limitations of Claim 54). This sequence has the motif of

Art Unit: 1634

LXXXXXXXXXE (claim 1ai). Position 2 has a S, position 5 has a L and position 4 is not an E, A, G or P (it is an R)(limitations of Claim 1, 12, 13, 24). .

Gelfand teaches the reverse transcriptase activity of the Tma DNA polymerase permits this enzyme to be used in methods for transcribing and amplifying RNA. Gelfand teaches combining an RNA template with a suitable primer under conditions whereby the primer will anneal to the corresponding RNA template, and reverse transcribing the TNA template by incubating the annealed primer-RNA template mixture with Tma DNA polymerase under conditions sufficient for the DNA polymerase to catalyze the polymeraseion of deoxyribonucleoside triphosphates to form a DNA sequence complementary to the sequence of the RNA template. Gelfand further teaches that Tma DNA polymerase has been found to be improved when contains Mn²⁺ compared to Mg²⁺. Thus, Gelfand teaches using Mg²⁺, while not most preferred method.

11. Claims 1, 8, 12-13, 20, 24-29, 36, 40-41, 48, 52-53, 55, 57, 59, 61, 63, 65, 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfand et al. (WO 92/06202, April 16, 1992).

Gelfand-1992 teaches a purified thermostable enzyme from eubacterium *Thermosipho africanus* (limitations of Claim 8, 20). The enzyme comprises LSKRIGLSVSE (positions 740-750 of sequence at page 9)(limitations of Claim 55, 59, 63, 67). This sequence has the motif of LXXXXXXXXXE (claim 1ai). Position 2 has a

Art Unit: 1634

S, position 5 has a I and position 4 is not an E, A, G or P (it is an R)(limitations of Claim 1, 12, 13, 24).

Gelfand teaches the reverse transcriptase activity of the Tma DNA polymerase permits this enzyme to be used in methods for transcribing and amplifying RNA. Gelfand teaches combining an RNA template with a suitable primer under conditions whereby the primer will anneal to the corresponding RNA template, and reverse transcribing the TNA template by incubating the annealed primer-RNA template mixture with Tma DNA polymerase under conditions sufficient for the DNA polymerase to catalyze the polymeraseion of deoxyribonucleoside triphosphates to form a DNA sequence complementary to the sequence of the RNA template. Gelfand further teaches that Tma DNA polymerase has been found to be improved when contains Mn²⁺ compared to Mg²⁺. Thus, Gelfand teaches using Mg²⁺, while not most preferred method.

12. Claims 1, 8, 12-13, 20, 24-29, 36, 40-41, 48, 52-53, 56, 57, 60- 61, 64-65, 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Swaminathan et al. (US Pat. 5,830,714, November 1998).

Swaminathan et al teaches a biologically active fragment of Bacillus stearothermophilus DNA polymerase. The polymerase is thermostable. As seen in Figure 2b and SEQ ID NO: 2, the sequence comprises LAQNLNISRKE. This sequence has the motif of LXXXXXXXXXE (claim 1ai). Position 2 has a S, position 5 has a I and position 4 is not an E, A, G or P (it is an R)(limitations of Claim 1, 12, 13, 24).

Swaminathan et al teaches comparing the reverse transcriptase activity of the DNA polymerase enzymes (col. 21, example 9). The reverse transcription assays were performed with nucleotides, enzyme, $MnCl_2$ or $MgCl_2$, primers (col. 21-23). Thus, Swaminathan et al teaches each of the limitations of the claimed invention.

13. Claims 1-4, 8-10, 12, 53, 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfand et al (EP 0 902 035 A2, March 17, 1999) as evidenced by Maniatis, "Molecular Cloning: Lab Manual" (page 214, 1982).

Gelfand et al. (herein referred to as Gelfand) teaches thermostable DNA polymerases. Gelfand teaches SEQ ID NO: 2, 3, 4, 5, 6, 7, namely SEQ ID NO: 2, 3, 4, 5, 6, 7, respectively of the instant application. Gelfand teaches that the "DNA synthesis reaction" refers to methods of producing copies of DNA including but not limited to PCR, strand displacement amplification, transcription mediated amplification, primer extension and reverse transcription (page 5). Gelfand exemplifies using the enzymes of the invention to efficiently incorporate nucleotides labeled with fluorescein family dye by means of a primer extension competitions assay (col. 10). Gelfand also teaches that the mutant polymerases may be used in sequencing methods. Gelfand teaches the method of DNA labeling by providing a thermostable DNA polymerase, providing a nucleotide labeled and performing a DNA synthesis reaction. The thermostable DNA polymerases of the invention are more suitable and desirable for use in processes such as DNA sequencing and in vitro synthesis of labeled products than prior art polymerases.

The claims specifically require a mixture comprising RNA. The words reverse transcription inherently are directed to transcribing an RNA template. By definition, reverse transcription is copying information found in RNA into DNA. Additionally, Claim 1 requires a mixture that comprises a primer. The instant specification states that "all known reverse transcriptases require a primer to synthesize a DNA transcript from an RNA template" (page 1, line 11-12). Thus, by definition, using a primer is an inherent property of reverse transcription. Finally, Maniatis, "Molecular Cloning: Lab Manual" teaches that divalent cations are an "absolute requirement for reverse transcriptase activity (page 214). Thus, by the patent describing reverse transcription, they are inherently teaching a template of RNA, a primer, a divalent cation at a temperature sufficient to initiate synthesis.

Therefore, since Gelfand teaches every limitation of the claimed invention, Gelfand anticipates the instant claims.

Response to Arguments

The response traverses the rejection. The response asserts that the rejection fails to point out, where in the experimental sections of these references the template for synthesis is an RNA molecule. This argument has been thoroughly reviewed, but is not found persuasive. The MPEP 2123 provides that "patents are relevant as prior art for all they contain. Specifically, "the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re

Art Unit: 1634

Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments.

The response clearly acknowledges that "the cited references clearly teach that the enzymes disclosed there can be used in a number of contexts and in many DNA synthesis reactions" (page 21 of response filed June 28, 2004). However, the response asserts that the cited definition fails to show that each of the activities listed in the definition is carried out by the same enzyme in the reaction mixture. This argument has been thoroughly reviewed, but is not found persuasive because it is unclear what the applicant asserts is missing. Gelfand specifically teaches that the thermostable polymerases having the structure recited may be used for performing DNA synthesis reaction. The patent specifically describes DNA synthesis reactions as encompassing reverse transcription. The art and the instant specification teaches that each of the other required elements are inherent in reverse transcription as described above.

Thus for the reasons above and those already of record, the rejection is maintained.

14. Claims 1-4, 8-10, 12, 53, 61, are rejected under 35 U.S.C. 102(e) as being anticipated by Gelfand et al (US Pat. 6,346,379, filed September 3, 1998) as evidenced by Maniatis, "Molecular Cloning: Lab Manual" (page 214, 1982).

Gelfand et al. (herein referred to as Gelfand) teaches thermostable DNA polymerases. Gelfand teaches SEQ ID NO: 2, 3, 4, 5, 6, 7, namely SEQ ID NO: 2, 3, 4,

Art Unit: 1634

5, 6, 7, respectively of the instant application. Gelfand teaches that the "DNA synthesis reaction" refers to methods of producing copies of DNA including but not limited to PCR, strand displacement amplification, transcription mediated amplification, primer extension and reverse transcription (col. 7, lines 25-30). Gelfand exemplifies using the enzymes of the invention to efficiently incorporate nucleotides labeled with fluorescein family dye by means of a primer extension competitions assay (col. 10). Gelfand also teaches that the mutant polymerases may be used in sequencing methods. Gelfand teaches the method of DNA labeling by providing a thermostable DNA polymerase, providing a nucleotide labeled and performing a DNA synthesis reaction. The thermostable DNA polymerases of the invention are more suitable and desirable for use in processes such as DNA sequencing and in vitro synthesis of labeled products than prior art polymerases.

The claims specifically require a mixture comprising RNA. The words reverse transcription inherently are directed to transcribing an RNA template. By definition, reverse transcription is copying information found in RNA into DNA. Additionally, Claim 1 requires a mixture that comprises a primer. The instant specification states that "all known reverse transcriptases require a primer to synthesize a DNA transcript from an RNA template" (page 1, line 11-12). Thus, by definition, using a primer is an inherent property of reverse transcription. Finally, Maniatis, "Molecular Cloning: Lab Manual" divalent cations are an "absolute requirement for reverse transcriptase activity (page 214). Thus, by the patent describing reverse transcription, they are inherently teaching

Art Unit: 1634

a template of RNA, a primer, a divalent cation at a temperature sufficient to initiate synthesis.

Therefore, since Gelfand teaches every limitation of the claimed invention, Gelfand anticipates the instant claims.

Response to Arguments

The response traverses the rejection. The response asserts that the rejection fails to point out, where in the experimental sections of these references the template for synthesis is an RNA molecule. This argument has been thoroughly reviewed, but is not found persuasive. The MPEP 2123 provides that "patents are relevant as prior art for all they contain. Specifically, "the use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments.

The response clearly acknowledges that "the cited references clearly teach that the enzymes disclosed there can be used in a number of contexts and in many DNA synthesis reactions" (page 21 of response filed June 28, 2004). However, the response asserts that the cited definition fails to show that each of the activities listed in the definition is carried out by the same enzyme in the reaction mixture. This argument has been thoroughly reviewed, but is not found persuasive because it is unclear what the

Art Unit: 1634

applicant is asserts is missing. Gelfand specifically teaches that the thermostable polymerases having the structure recited may be used for performing DNA synthesis reaction. The patent specifically describes DNA synthesis reactions as encompassing reverse transcription. The art and the instant specification teaches that each of the other required elements are inherent in reverse transcription as described above.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 11, 13-16, 20-32, 36-44, 48-52, 54-60, 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand et al (US Pat. 6,346,379, filed September 3, 1998) or Gelfand et al (EP 0 902 035 A2, March 17, 1999) in view of Kawasaki (PCR Protocols, Chapter 3, pages 21-27, 1990).

Each of the Gelfand et al. (herein referred to as Gelfand) references teaches thermostable DNA polymerases. Gelfand teaches SEQ ID NO: 2, 3, 4, 5, 6, 7, namely SEQ ID NO: 2, 3, 4, 5, 6, 7, respectively of the instant application. Gelfand teaches that the "DNA synthesis reaction" refers to methods of producing copies of DNA including but not limited to PCR, strand displacement amplification, transcription mediated

Art Unit: 1634

amplification, primer extension and reverse transcription (col. 7, lines 25-30). Gelfand exemplifies using the enzymes of the invention to efficiently incorporate nucleotides labeled with fluorescein family dye by means of a primer extension competitions assay (col. 10). Gelfand also teaches that the mutant polymerases may be used in sequencing methods. Gelfand teaches the method of DNA labeling by providing a thermostable DNA polymerase, providing a nucleotide labeled and performing a DNA synthesis reaction. The thermostable DNA polymerases of the invention are more suitable and desirable for use in processes such as DNA sequencing and in vitro synthesis of labeled products than prior art polymerases.

Gelfand does not specifically teach a method of reverse transcription using magnesium, primers and DNA polymerase.

However, Kawasaki teaches amplification of RNA methods which employ PCR buffer comprising magnesium, namely $MgCl_2$. Kawasaki teaches that the "magnesium concentration is also critical, so care should be taken that the addition of reagents does not lower the magnesium molarity" (page 26). Kawasaki teaches that "the source and type of reverse transcriptase do not seem to be of critical importance." Kawasaki teaches incubating the reaction mixture at 23 and 42 degrees. Kawasaki teaches performing PCR following the reverse transcriptase reaction.

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have used the mutant polymerases taught by Gelfand to be useful in reverse transcription assays using the specific method of Kawasaki. The ordinary artisan would have recognized that the method provided by Kawasaki was a

Art Unit: 1634

standard method of RNA amplification. Since Kawasaki clearly indicates that the source and type of reverse transcriptase does not appear to be critical, the ordinary artisan would have been motivated to have substituted the mutant DNA polymerases of Gelfand because they have demonstrated increased efficiency.

Response to Arguments

The response traverses the rejection. The response asserts that nothing in the cited references suggest that the enzymes of Gelfand would be useful in the buffer of Kawasaki. This argument has been reviewed but is not convincing because Kawasaki teaches that "the source and type of reverse transcriptase do not seem to be of critical importance."

The response asserts that the first reports of reverse transcription catalyzed by thermostable DNA polymerases was inefficient and insensitive. This argument has been thoroughly reviewed, but is not found persuasive because the claims are not drawn to any particular concentration of magnesium. Thus, the prior art does teach the use of magnesium in RT PCR assays and the teachings in the art to use magnesium and that divalent cations are an absolute requirement for reverse transcriptase activity, the ordinary artisan would have included magnesium within the RT-PCR assay as required by the claims.

The response filed June 28, 2004 states that it is not clear what was meant by the remarks of unexpected results must be commensurate in scope with the claims. As provided by MPEP 716.02(d) Unexpected Results must be Commensurate in Scope with Claimed Invention. The MPEP states, "whether the unexpected results are the

Art Unit: 1634

result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range."

Here, the specification teaches a single example using the native Tth DNA polymerase and each of the mutants. The specification does not show that over the entire range, the unexpected results.

With respect to the teachings in the specification and the art, the large number of species within the genus would have the unexpected properties provided for Tth DNA polymerase.

Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

16. No claims allowable over the art.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Goldberg
9/23/04